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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

Docket Number FSIS-2013-0029

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Availability of FSIS Compliance Guidelines for Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration Through Labeling

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of an updated version of the Agency's compliance guidelines for controlling hazards posed by allergens and other ingredients of public health concern. The guidelines provide recommendations for identifying hazards when conducting a hazard analysis and for preventing and controlling hazards through a hazard analysis and critical control point (HACCP) plan or Sanitation standard operating procedures (SOPs) or other prerequisite programs with respect to these substances.

ADDRESSES: A downloadable version of the revised compliance guide is available to view and print at [\[http://www.fsis.usda.gov/wps/wcm/connect/f9cbb0e9-6b4d-4132-ae27-53e0b52e840e/Allergens-Ingredients.pdf?MOD=AJPERES\]](http://www.fsis.usda.gov/wps/wcm/connect/f9cbb0e9-6b4d-4132-ae27-53e0b52e840e/Allergens-Ingredients.pdf?MOD=AJPERES). No hard copies of the compliance guidelines have been published.

FOR FURTHER INFORMATION CONTACT: For further information contact Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250-3700, (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On April 21, 2014, FSIS published a Federal Register notice (79 FR 22083) announcing the availability of and opportunity to comment on Agency guidance on allergens and other ingredients of public health concern. FSIS explained that in recent years (2008-2012), there had been a sustained increase in the number of recalls of FSIS-regulated product that contained undeclared allergens, and that these recalls were preventable as many had been the result of ingredient changes, product changes, products in the wrong package, or products with misprinted labels. The Agency also explained that the consumption of meat and poultry products containing ingredients of public health concern, such as undeclared allergens, may result in adverse health outcomes for certain individuals.

The Agency explained that it was issuing the guidelines to provide meat and poultry establishments with recommendations on how to identify hazards with respect to allergens and other ingredients of public health concern when conducting their

hazard analysis, how to prevent and control these hazards through HACCP plans, Sanitation SOPs, or other prerequisite programs, and how to properly declare allergens in product. The guidelines also provided information on proper procedures for processing, handling, storing, and labeling a product with an allergenic ingredient or ingredient of public health concern.

In addition, the Agency explained that the guidelines represent the best practice recommendations of FSIS, based on scientific and practical considerations, and that the recommendations are not requirements. FSIS said that by following the guidelines, establishments would be likely to ensure that product labels declare all ingredients, as required in the regulations, and that the product would not contain undeclared allergens or other undeclared ingredients. FSIS recommended that establishments consider incorporating the guidelines in their HACCP plan or Sanitation SOPs or other prerequisite programs.

Updated Guidelines:

FSIS has updated the guidelines to include numbered appendices for diagrams, checklists, and supplemental information to simplify locating these references. In response to the comments discussed below, FSIS updated the guidelines by:

- clarifying, on pages 2 and 4, that the focus of the document is on FSIS-regulated establishments, state-

regulated establishments, and operations where all or part of the premises meet the "food processing plant" definition, as defined in the Food and Drug Administration's (FDA) "2013 Food Code";

- clarifying, in Section 1.2, page 5, that sulfur-based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten, and monosodium glutamate (MSG) are ingredients of concern that may result in adverse reactions in certain susceptible individuals, yet they are not considered allergens;
- revising the "What is a letter of guarantee (LOG)?" box on page 8, and adding a paragraph on page 9 to clarify and describe a LOG, the difference between a LOG and a Certificate of Analysis (COA), and the communication and coordination between an establishment and its suppliers that FSIS recommends when an establishment relies on LOGs;
- adding "Allergenic Ingredients and Foods," a listing of allergenic ingredients and foods that may contain allergenic ingredients, as a resource (Appendix 6);
- adding "Tips for Avoiding Your Allergen," published by Food Allergy Research and Education (FARE) to the "References and Resources" section (Appendix 7); and

- adding FSIS Directive 8080.1,
“Recall of Meat and Poultry Products,” to the
“References and Resources” section (Appendix 7).

In addition, in Section 2.1, FSIS edited the text to emphasize the purpose of a hazard analysis and a hazard identification. Under Section 2.3, FSIS edited the third paragraph to delete that an establishment include storage in its HACCP system because that guidance is included in the first paragraph of this section. Also, in Section 2.3, FSIS added the recommendation that an establishment conduct simulations with inaccurate product labels to test system, checklists, and procedures as a step to prevent mislabeling during packing, labeling, and storage of the final product.

Comments and Responses

FSIS received a total of seven comments in response to the April 2014 Federal Register notice and guidelines. The commenters included consumer and trade organizations, individuals, and a professional organization. The comments and the Agency’s responses are discussed below.

Comment: A professional organization recommended that FSIS modify the introductory sections of the document to clarify that the compliance guidelines were developed for a processing setting.

Response: FSIS has modified the introductory sections of the guidelines to clarify that the emphasis of the document is on FSIS-regulated establishments, state-regulated establishments, and operations where all or part of the premises meet the food processing plant definition as defined in the FDA "2013 Food Code," available online at (<http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf>).

Comment: An individual commented that Attachment 3 to FSIS Notice 29-13, "Allergenic Ingredients and Foods," is very useful, especially to very small meat and poultry establishments, including those that are dual jurisdiction processing establishments, and that it should be included in the compliance guidelines.

Response: The attachment, entitled, "Allergenic Ingredients and Foods," is based on "Tips for Avoiding Your Allergen," published by Food Allergy Research and Education (FARE). FSIS Notice 29-13 was issued in April 2013 and is now expired. FSIS agrees that the attachment provides useful information and has included it in the guidelines as Appendix 7.

Comment: A consumer group recommended clarifying that some of the ingredients listed under Section 1.2 are not allergens, and that monosodium glutamate (MSG) should not be included

because research has not confirmed that it causes adverse reactions.

Response: The list of ingredients in Section 1.2 has been modified to clarify that sulfur-based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten, and monosodium glutamate (MSG) are ingredients that may result in an adverse reaction in certain susceptible individuals, yet they are not considered allergens. FSIS is concerned about all foods or food ingredients that may cause adverse health effects. Therefore, MSG remains an ingredient of public health concern.

Comment: A trade group recommended that, to ensure that industry is aware of the recommendations in the compliance guide, FSIS provide outreach to the meat and poultry industry.

Response: FSIS intends to provide outreach to the meat and poultry industry on the compliance guidelines by conducting web-based (webinar) sessions for industry and announcing the compliance guide recommendations on the FSIS Small Plant News Webpage at <http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/small-plant-news/small-plant-news>.

Comment: One commenter requested that FSIS require the listing of all spices by name on product labels. The commenter stated that spice allergies are significant health concerns and that food labels need to specifically list all spices in the

product. The commenter was specifically concerned with the labeling of garlic.

Response: The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) require the listing of the common or usual name of ingredients on product labels, except that spices and flavorings may be designated as "spices" and "flavorings," without naming each ingredient. Therefore, FSIS does not have the legal authority to require the listing of each spice or flavoring. The term "spice" is defined in the FSIS labeling regulations (9 CFR 317.2(f)(1)(i)(A) and 381.118(c)(1)) to mean any aromatic vegetable substance in the whole, broken or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional, and from which no portion of any volatile oil or other flavoring principle has been removed. In addition, the terms "natural flavor," "natural flavoring," "flavor," or "flavoring" may be used to designate spices as well as powdered garlic, powdered onion, or celery powder, specifically. If whole or broken garlic is used in the formulation of the product, it would need to be declared in the list of ingredients.

Comment: Two trade organizations commented that throughout the guidelines, the focus was on the "Big Eight" allergens with little discussion of the ingredients of concern that may cause

adverse reactions in susceptible individuals. The commenters recommended that a list of ingredients of public health concern be created in collaboration with the National Institute of Allergy and Infectious Diseases or similarly informed entity.

Response: FSIS is concerned about all foods or food ingredients that may cause adverse health effects. These include the "Big Eight" ingredients as well as other ingredients of concern. As discussed above, FSIS has modified the list of ingredients in Section 1.2 to clarify that sulfur-based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten, and monosodium glutamate (MSG) are ingredients of concern that may cause adverse reactions in certain susceptible individuals. However, FSIS has not established a list of all ingredients to which consumers have reported adverse reactions. Establishments are required to be aware of the ingredients they are using in the production of their products and to determine whether the ingredients may trigger food sensitivities. They need to employ the necessary in-plant controls to prevent cross-contact and assure accurate label declarations.

In addition, FSIS Directive 8080.1, "Recall of Meat and Poultry Products," lists factors considered by the FSIS Recall Committee when evaluating the public health significance of an undeclared ingredient in a meat or poultry product. The directive lists the questions and other factors that the Agency

considers. Although the Directive provides instructions to FSIS personnel, the questions that the FSIS recall committee considers will be helpful to industry also. Therefore, the Directive has been added to the "References and Resources" section (Appendix 7).

Comment: A trade organization recommended that the list of undeclared allergen recalls include the corrective actions taken to ensure that allergens appear on the label.

Response: FSIS agrees that providing undeclared allergen corrective action scenarios could be a useful mechanism to ensure that allergens appear on the label. "Allergen Scenarios and Possible Prevention Measures," Appendix 5 of the compliance guidelines, is based on historical recalls, giving some insight into the possible preventive measures that would have prevented the undeclared allergen.

Comment: Two trade organizations commented that requiring establishments to review ingredient lists on a continuous basis, especially when an establishment has changed suppliers, or the supplier has modified the ingredient formula, would create unjustified increases in manufacturing cost. They additionally commented that a review of letters of guarantee should not be confused with certificates of analysis.

Response: FSIS has edited the "What is a letter of guarantee (LOG)" box on page 8 of the guidelines, as well as the

description of recommendations on page 9 to clarify what are Letters of Guarantee. As mentioned above, establishments are required to be aware of the ingredients they are using in the production of their products and to determine whether they have considered and employed the necessary in-plant controls to prevent cross-contact and assure accurate label declarations. LOGs are a means to prevent the possible inclusion in the product of an allergen that is not declared on the product label. If a LOG is only a general statement, the establishment should consider initiating a dialogue with its suppliers to ensure the establishment understands ingredient information or to recommend that more specific information be included in LOGs. However, these are guidelines, and FSIS is not establishing any new requirements.

Comment: Two trade organizations commented that if the Agency is suggesting that testing is the only way to meet the guidelines, the guidelines are regulatory requirements that should follow proper rulemaking procedures. The commenters stated that examples of cleaning controls and procedures of sanitation verification should be provided in the guidelines. They also recommended that testing ingredients should only be done in cooperation and knowledge of the supplier to ensure that related product is properly held.

Response: Because some FSIS-regulated establishments conduct testing for allergens in their products, page 12 of the guidelines includes information about the test kits and the use of reference laboratories. As stated in the guidelines, allergen testing may be considered to verify and document sanitation effectiveness. As also noted in the guidelines, testing is not the only way to demonstrate that allergens are not presented on a production line, on equipment, or in product, Section 2.2 specifically addresses sanitation. Therefore, testing is not required, and the guidelines do not represent regulatory requirements.

When establishments conduct allergen testing of ingredients, FSIS encourages communication with the supplier. Also, FSIS recommends that establishments hold or control product tested for allergens until they receive results, although doing so is not required. Establishments should design their food safety system within their available resources to take all necessary and practical steps to ensure that only safe product enters commerce.

Comment: Two trade organizations commented that proper labeling and packaging of products constitutes product separation. They stated that recommending unrealistic definitions of separation would be an unwarranted expense that would not effectively correct the cause of allergen recalls.

Response: Properly labeling and packaging products is essential and required by FSIS regulations and authorizing statutes. As an additional preventive measure, as stated in the guidance, establishments should consider whether the identification and separation of products would effectively prevent employees from selecting the wrong ingredient during formulation, the wrong label, or the wrong product.

Comment: Two trade organizations commented that the compliance guideline establishes regulatory requirements. They recommended that the document more clearly state that the practices in the compliance guidelines are neither regulatory requirements nor the only way to control and prevent undeclared allergens in the production process.

Response: The compliance guidelines are intended to inform industry about effective and innovative methods to address the problem of undeclared allergens and ingredients of public health concern. The document does not establish any new requirements that industry must follow, but rather it is intended to assist establishments in meeting the existing FSIS labeling and HACCP regulations.

The compliance guidelines provide recommendations, not requirements, to establishments for identifying hazards when conducting a hazard analysis and for preventing and controlling hazards with respect to allergens and other ingredients of

public health concern through the implementation of HACCP plans, sanitation SOPs, or other prerequisite programs. The guidelines were edited to clarify that the document consists of recommendations, not requirements.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Done, at Washington, DC on: November 9, 2015.

Alfred V. Almanza,
Acting Administrator.

